EFSPI/PSI SIG on data transparency

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EFSPI leadership meeting Brussels 1. July 2015

Overview

- Short overview on status of data sharing SIG

- Discussion round on data sharing: How can we utilize this further?

  - Internal data sharing?
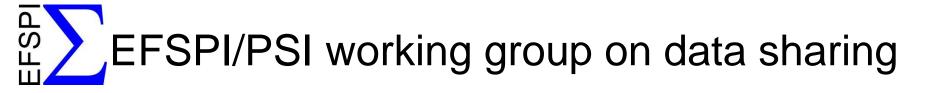
EFSPI/PSI working group on data sharing

- Lead Sally Hollis and Uli Burger
- Objectives:
  - To identify and prospectively prioritize statistical issues in data transparency
  - To co-ordinate statistical contributions across Europe to the data transparency debate
  - To disseminate relevant information on the topic across the statistical community
  - To develop and share a vision of the potential longer term impact of data transparency.

EFSPI/PSI working group on data sharing

- Five work streams
  - Providing continuous input in EMA/EFPIA (Christoph Gerlinger, Bayer, Chrissie Fletcher, Amgen)
  - Recommendations for minimal analysis practices (Sally Hollis, AstraZeneca, Chrissie Fletcher, Amgen)
  - Future impact on biostatistics (Nick Manamley , Amgen)
  - Minimal requirements for data sharing (Rebecca Sudlow , Roche, Janice Branson, Novartis)
  - Ensuring patient data confidentiality (Katherine Tucker, Roche)

EFSPI/PSI working group on data sharing

- Status:
  - All subgroups close to finalization
  - Four manuscript in preparation (first work stream never anticipated publication)
  - Goal: To publish all four manuscripts together with an accompanying introduction during this year

General activities

- Data sharing is still a very important topic in the statistical community
  - One day BBS/EFSPI meeting in Basel Nov 14
  - Many sessions at statistical conferences
- Data sharing implemented in most companies and becoming reality
- Requests coming but perhaps still at lower level than anticipated

Update on data sharing requests

Number of research proposals	126 (30.April 2015)	
Requirements check	Finished	93
	Ongoing	11
	Withdrawn by requestor	12
	Rejected	10
IRP review	Approved with or without conditions	85
	Rejected or advised to resubmit	8
Data sharing agreement	Ongoing	23
	Signed	60
	Not agreed	0
	Withdrawn by requestor	2

Ref: https://www.clinicalstudydatarequest.com/Metrics.aspx

General status

- Data sharing is helping to provide transparency

- Reputation of Pharma has increased, at least partly (quick implementation, data sharing pretty extensive)

- But impact on Pharma beyond these early gains still not evaluable

Potential impact

- Data sharing activities in companies often driven by biostatistics
- High integrity of biostatistics helped companies to handle transparency
  - Impact of biostatistics highlighted
- Still to be seen: Impact on companies when results of data sharing comes back. Not all companies are prepared for that

Potential impact

Some opportunities:

- More internal and cross-industry sharing
- Increased credibility
- More interactions with academia
- Job security
- Interesting new role for some statisticians
- Biostatistics influence could grow further in marketed products

Some threats:

- More work to assess resulting publications
- Biostatistics not prepared for investigation of resulting publications
- Need more resources and different profile of statisticians
- Quality of resulting research could be poor with confusing impact on societies

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Discussion

- What is the status at your company and the impact for statistics?

- Are you preparing for further work coming out of data sharing?

- Are you thinking about opportunities for internal and cross-industry sharing?

- Should EFSPI stay heavily involved in this topic? Or have we done the work?